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PATENT Case No. 21170P

JC09 Rec'd PCT/PTO 12 OCT 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Jun-Hong Chou, et al.	· ·
Serial No. PCT/US04/11211 Filed: April 12, 2004 . For: POLYMORPHIC FORM OF MONTELUKAST SODIUM	Art Unit: Examiner:

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97

Sir:

- 1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).
- 2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.
- 3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.
- 4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

EXPRESS MAR CERTIFICATE
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5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

	RELATED APPLICATION				
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE			
					
					

If this is inconvenient, additional copies will be submitted upon request. 6. In accordance with 37 C.F.R. 1.97, (check one) the attached information is filed within three months of the filing date of the captioned case. the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits. the attached information is filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114. the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action, Notice of Allowance, or an action that otherwise closes prosecution in the application. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p). each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement. each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the information disclosure statement. no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,

Attorney For Applicant(s)

Reg. No. 32,718 MERCK & CO., INC.

MERCK & CO., INC. Patent Dept., RY60-30

P.O. Box 2000

Rahway, N.J. 07065-0907

(732)594-6343

Date: 00, 12, 2005

Approved for use through 7/5/1/2007. 0A/B-0651-2035. STITUTE for PTO/SB/08A (07-05), Information Disclosure Statement by Applicant

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3	STATEMENT BY APPLICANT			First Named Inventor	Jun-Hong Chou	1
			,	Group Art Unit		1
(use as many sheets as necessary)			necessary)	Examiner Name		1
Sheet	1	of	2	Attorney Docket Number	21170P)

			U.S. PA	ATENT DOCUMENTS	
Examiner Cite No.		e U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		5,565,473		Michel L. Belley, et al.	10/15/1996
		5,614,632		Mahadevan Bhupathy, et al.	03/25/1997
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	FOREIGN PATENT DOCUMENTS								
			Foreign Patent Docume	ent		Date of Publication of			
Examiner Cite Initials* No.	Office	Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY				
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Examiner Signature Date Considered

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STITUTE for PTO/SB/0SA (07-05), Information Disclosure Statement by Applicant

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					Jun-Hong Chou			
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	<u></u>			Examiner Name				
Sheet	2	of	2	Attorney Docket Number	21170P)	

	NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.					
	J	ELLIOTT ISRAEL, MD, et al., Effects of Montelukast and Beclomethasone on Airway Function and Asthma Control, J. Allergy Clin. Immunol., Vol. 110, pp 847-854, December (2002).					
	✓	CHESTER J. KITCHEN, et al., <u>A Semi-Automated 96-Well Protein Precipitation Method for the Determination of Montelukast in Human Plasma Using High Performance Liquid Chromatography/Fluoroescence Detection</u> , J. Pharm. Biomed. Anal., Vol. 31, pp 647-654, January (2003).					

Examiner Signature	Date Considered	

^{*}Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.